510(k) Summary

In accordance with 21CFR807.92, the following summary of information is provided;

Date June 26th 2012

Submitter: ALPINION MEDICAL SYSTEMS Co., Ltd.

Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd),

Guro-gu, Seoul, Republic of Korea 152-848,

Primary Contact Person Donghwan Kim

QARA Manager

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Secondary Contact Yuchi Chu

Person Address: Suite 229, 10604 NE 38th Place, Kirkland, WA 98033,

United States Phone: 425 949 4907 Fax: 425 949 4908

Email: ychu@alpinionus.com

Device Trade Name: E-CUBE 15

<u>Common/Usual Name:</u> Ultrasonic Pulsed Doppler Imaging System

Classification Names System, Imaging, Pulsed Doppler Ultrasonic

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-

IYN

Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO , IYN

Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX

Predicate Device(s) K120060 E-CUBE 9 Diagnostic Ultrasound System

Device Description:

E-CUBE 15 product is an ultrasound imaging system for medical diagnosis. The system platform provides optimal patient diagnosis workflow with the 18.5° wide flat panel display, ergonomic control panel with easy user Interface, optimal image quality.

Indications For Use:

The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Small Organ (breast, testes, thyrold); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult); Peripheral Vascular (PV); and Urology (including prostate).

Technology: E-CUBE 15 employs the same fundamental scientific technology as its predicate device.

Feature 510(k)	Proposed E-CUBE 15 ALPINION MEDICAL SYSTEMS Co., Ltd.	Predicate E-CUBE 9 ALPINION MEDICAL SYSTEMS Co., Ltd.
Number	-	K120060
Indications for use	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal Superficial); Cardiac (adult); Peripheral Vascular (PV); Urology (including prostate).	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal(Superficial); Cardiac (adult & pediatric); Peripheral Vascular (PV); Urology (including prostate).
	 Discussion of differences The individual functions of E-CUBE 15 effectiveness same as E-CUBE 9, eve the indications comparing with the pred Therefore, E-CUBE 15 substantially ed 	has essential performance and safety n though E-CUBE 15 as limited scope of dicate. quivalent with predicate device.
Dimensions and weight	Weight: approx. 105kg Height: 1413/1848 mm Width: 585mm Depth: 670mm	Weight: approx. 89.5kg Height: 1340/1600 mm Width: 590mm Depth: 850mm

Manitar	18.5" Wide LCD	478 MARIA LOD
Monitor	18.5 Wide LCD	17" Wide LCD 18.5" Wide LCD
	Display size: 1366 X 768	Display size: 1366 X 768
	Recording area: 880 X 660	Recording area: 880 X 660
1	Necording area. 666 × 666	Recording area. 600 X 600
·	Adjustable Tilt/Swivel, up/down, rotate	Adjustable Tilt/Swivel, up/down, rotate
	Digital Brightness/Contrast Adjustment	Digital Brightness/Contrast Adjustment
Electrical	Voltage: 100~120V, 200~240V	Voltage: 100~120V, 200~240V
power	Frequency: 50/60Hz	Frequency: 50/60Hz
	Power: Max. 900 VA with Built-in and	Power: Max. 600 VA with Built-in and
	On-Board Peripherals	On-Board Peripherals
Consol design	3 active Probe Ports	• 3 active Probe Ports
	(4 Probe Ports Option)	
	Touch panel	
	• Integrated HDD (Capacity: 500G)	Integrated HDD (Capacity: 500G)
	• Integrated DVD-R/W Drive	Integrated DVD-R/W Drive
·	On-board Storage for Peripherals BW Printer	On-board Storage for Peripherals
	Color Printer	- B/W Printer Color Printer,
	DVD recorder	DVD recorder
	Control panel lift mechanism	Control panel lift mechanism
	• 5 Transducer holders, detachable for	• 5 Transducer holders, detachable for
	cleaning and washing	
	Integrated Gel warmer	cleaning and washing
l a	, •	Integrated Gel warmer
	- 3 temperature levels	- 3 temperature levels
	• Front Handle	Front Handle
	Rear Handle	Rear Handle
	Wheel-lock Mechanism	Wheel-lock Mechanism
	- Front & BackWheel: Total lock	- Front & Back -Wheel: Total lock
	8 USB ports: Touch module side (2ea)	• 5 USB ports: Front Side (1ea) Back
	Back side (6ea)	side (6ea)
	Thumbnail images on-screen	Thumbnail images on-screen
	On-line Help key	On-line Help key
	• ECG Module	• ECG Module
	Patient ECG Lead Wires	Patient ECG Lead Wires
	Discussion of differences	
	F-CUBE 15 has 3 or 4 (ontional) probe	ports, 8 USB ports: Touch module side
	(2ea) Back side (6ea) and Touch namel	But, E-CUBE 9 has 3 probe ports and 5
	USB ports: Front Side (1ea) Back side	(6ea). It is not related with the safety,
	effectiveness and essential performance.	(000). It to that foliates watt the salety,
Operating	• B-Mode	• B-Mode
		• M-Mode
Mode	• M-MDDA	
Mode	• M-Mode	
Mode	Anatomical M-mode	- Anatomical M-mode
Mode	Anatomical M-mode Pulsed Wave (PW) Doppler with High	Anatomical M-mode Pulsed Wave (PW) Doppler with High
Mode	Anatomical M-mode Pulsed Wave (PW) Doppler with High PRF	Anatomical M-mode Pulsed Wave (PW) Doppler with High PRF
Mode	Anatomical M-mode Pulsed Wave (PW) Doppler with High	Anatomical M-mode Pulsed Wave (PW) Doppler with High

	Power Doppler Mode	Power Doppler Mode							
1	• THI (PI/FTHI)	• THI (PI/FTHI)							
	Tissue Doppler Imaging	Tissue Doppler Imaging							
	Beam Steering	Beam Steering							
	Panoramic B/CF	Panoramic B/CF							
1	Spatial compounding	Spatial compounding							
	Frequency compounding	Frequency compounding							
	Xpeed on 2D / CF/PW	· Xpeed on 2D / CF/PW							
	Auto IMT	• Auto IMT							
ľ	Auto traces PW	Auto traces PW							
	Directional Power Doppler Mode	Directional Power Doppler Mode							
·I	• SRI	• SRI							
	• Full SRI	• Full SRI							
	• ECG	• ECG							
	- 200								
		• 3D/4D Volume Mode							
i	Discussion of difference								
	3D/4D is an image representation of	f a volume or 3D object, such as the heart							
	or fetus. Surface rendering can be u	ised to visualize surfaces. Another image							
	presentation is volume rendering, in	which surfaces can be semitransparent or							
	2D slice planes through the object. Alternatively, there is simultaneous								
	of different 2D-slice planes (side by side	de).							
	E-CUBE 15 includes essential establishment.	operating mode for diagnosis and is							
Labeling	Goodaniany Equivalent.	1							
and/or	0.4. 00.0.1. 0.00.0.0								
promotional	Section 6B Catalog E-CUBE 15	Section 3C Catalog E-CUBE9							
materials									
Accessories or	- Control of the cont	Color printer							
kits	BW printer	B/W printer							
}	DVR	DVR							
1	DVD -RW	DVD -RW							
	Footswitch	Footswitch							
	Probe Holder	Probe Holder							
;	Ultrasonic gel	Ultrasonic gel							
1.	Cidex OPA (disinfectant agents)	Cidex OPA (disinfectant agents)							
	Cidex Plus (disinfectant agents)	Cidex Plus (disinfectant agents)							
	SC1-6 Biopsy guide kit	SC1-6 Biopsy guide kit							
	L3-12 Biopsy guide kit	L3-12 Biopsy guide kit							
	E3-10 Reusable Biopsy needle guide	E3-10 Reusable Biopsy needle guide							
	E3-10 Disposable Biopsy needle guide	E3-10 Disposable Biopsy needle guide							
	ECC Module								
1	ECG Module	ECG Module							
1	Patient ECG Lead Wires	Patient ECG Lead Wires							
		, anon coo com vines							

Measurement	1. General	1. General .							
and	1) B-Mode	1) B-Mode							
Calculation	2) M-Mode	2) M-Mode							
functions	3) Doppler Mode	3) Doppler Mode							
	2. Abdomen	2. Abdomen							
	1) B-Mode	1) B-Mode							
	2) M-Mode	2) M-Mode							
	3) Doppler Mode	3) Doppler Mode							
	3. Small Parts	· 3. Small Parts							
•	1) B-Mode	1) B-Mode							
	2) M-Mode	2) M-Mode							
	3) Doppler Mode	3) Doppler Mode							
1	4. Obstetrics	4. Obstetrics							
	1) B-Mode	1) B-Mode							
	2) M-Mode:	2) M-Mode:							
	3) Doppler Mode	3) Doppler Mode							
	5. Gynecology	5. Gynecology							
	1) B-Mode	1) B-Mode							
	2) M-Mode:	2) M-Mode:							
	3) Doppler Mode	3) Doppler Mode							
	6. Cardiology	6. Cardiology							
	1) B-Mode:	1) B-Mode:							
	2) M-Mode	2) M-Mode							
	3) Doppler Mode	3) Doppler Mode							
	7. Vascular	7. Vascular							
	1) B-Mode	1) B-Mode							
	2) M-Mode	2) M-Mode							
	3) Doppler Mode	3) Doppler Mode							
	8. Urology	8. Urology							
	1) B-Mode	1) B-Mode							
	2) M-Mode	2) M-Mode							
	3) Doppler Mode								
	by Copplet Mode	3) Doppler Mode							
		1) B-Mode							
		2) M-Mode							
	Discussion of difference	3) Doppler Mode							
	- Distribution of mileterize								
	Measurement and Calculation functions of E-CUBE 15 are not include Pediatrics.								
•	It is not related with the safety eff	fectiveness and essential performance.							
Acoustic	Track 3	Track 3							
output		112011 0							

<Conclusion>

The indications for use, material, form factor, performance, and safety characteristics between E-CUBE 15 and the predicate device are the same except for Pediatric, Cardiac (pediatric). The primary difference is cosmetic structure and component used only. Therefore, we can claim the substantially equivalence of E-CUBE 15 to the predicate device.

<u>Determination of Substantial Equivalence:</u>

Summary of Non-Clinical Tests:

E-CUBE 15 has been evaluated for biocompatibility, acoustic output as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. E-CUBE 15 and its application comply with voluntary standards as detailed in this premarket submission. The following quality management system measures were applied to the development of E-CUBE 15:

- NEMA UD2, UD3
- AIUM Medical Ultrasound Safety
- IEC60601-1
- IEC60601-1-2
- IEC60601-2-37 (3rd Edition)
- ISO 10993-1

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, E-CUBE 15, did not require clinical studies to support substantial equivatence.

Conclusion:

Alpinion Medical Systems Co., Ltd. considers E-CUBE 15 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

ALPINION MEDICAL SYSTEMS Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA or the requirements will be published in guidance documents.

Appendix B - Decision Summary for Web Posting

Decision Summary, K 121888

This 510(k) was reviewed under OIVD's Pilot Triage Program. This program represents an internal workload management tool intended to reduce internal FDA review resources for 510(k) applications that are of good quality upon receipt by FDA.

The information in the 510(k) is complete and supports a substantial equivalence (SE) determination. Please refer to the applicant's 510(k) summary for a summary of the information that supports this SE determination.



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Mr. Donghwan Kim QARA Manager Alpinion Medical Systems Co., Ltd. 1, 6, and 7FL Verdi Tower 72, Digital-ro (St) 26-gil (Rd), Guro-gu SEOUL 152-848 REPUBLIC OF KOREA

SEP 2 5 2012

Re: K121888

Trade/Device Name: E-CUBE 15 Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYO, IYN, and ITX

Dated: June 26, 2012 Received: June 28, 2012

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of July 26, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the E-CUBE 15, as described in your premarket notification:

Transducer Model Number

<u>SC1-6H</u>	<u>L8-17X</u>
L3-12H	<u>SC1-4H</u>
<u>SP1-5X</u>	E3-10H

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris

Director

Division of Radiological Devices
Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

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Enclosure(s)

Indications for Use

510(k) Number (if knawn):
Device Name: E-CUBE 15
Indications for Use:
The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Small Organ (breast, teste thyroid); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult); Peripher Vascular (PV); and Urology (including prostate).
Prescription Use AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C) (PLEASE DO NOT WRITE BELOW THIS UNE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD) (Owlsion Sign-Oif) Division of redictological Devices Office of In Vitro Diagnostic Devices Evaluation and Safety
610K. K121888

E-CUBE 15 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	8	M	PWD	CWO	Galor Doppler	Pawer Dopplar	Tissue Harmonic imaging	Combined* (Specify)	Other" (Specify)	
Ophinalmic										
Fetal	N	N	N	<u> </u>	N	N	N	N		
Abdominal	N	N	N		N	N	N	N		
Intra-operative (Specify)										
intre-operative (Neuro)	П	Г								
Laparoscopic		Г								
Pediatric	\Box									
Smell Organ (breast, testes, thyroid)	N	N	N		N	N	N	N		
Neonatal Caphallo		\Box								
Adult Cephalic		Γ								
Trans-rectal	N	N	N		N	N	N	N		
Trans-veginal	N	N	N		N	N	N	Ν.	<u> </u>	
Trans-wethrel										
Trans-esoph. (non-Card.)	Г	T								
Musculo-skeletal (Conventional)	N	N	N		N	N	N	N		
Muscuko-ekeletal (Superficial)	N	N	N		N.	N	N	N		
Intravescular	Τ	1		T				<u> </u>		
Cardiac Adult	N	N	N	N	N	N	N	N		
Cardiac Pediatric		T								
Intravascular (Cerdiac)		Т							 	
Trans-esoph. (Cardisc)	T	Т								
Intra-cardiac	\top	T							<u> </u>	
Peripheral vessel	N	N	N		И	N	N	N		
Urology (Including prostate)	N	H	N		N	N·	N	N	1	

N = new indication; P = previously cleared by FDA; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (CIVD)

Prescripton User (Par 21 CFR 601.109)	
ALPINION MEDICAL SYSTEMS Co., Ltd.	E
(Division Sign-Oth) Division of Registergional Devices	
Office of in Vitro Diagnostic Device Evaluation and Safety	

^{*} Combinad: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: \$D, 4D

E-CUBE 15 with SC1-6H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Calor Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophtheimic		Γ							
Fetal	N	N	N		N	N	N	N	
Abdominal	N	N	Ň		N	N	N	N	
Intra-operative (Specify)		Г							
Intra-operativa (Nauro)	1	Г							
Laparescopic		Г							
Pediatric	T								
Small Organ (breast, testes, thyroid)									
Neonstal Caphalic	1	Н		 					
Adult Caphalic		1							
Trans-rectal	1			<u> </u>					
Trans-veginal	1	1		· · ·					
Trans-weithfal	_								
Trans-esoph. (non-Card.)	1								
Musculo-skeletsi (Conventional)									
Musculo-akoleta) (Superficial)									
Intrevascular	T	Г							
Cardiac Adult									
Cardiso Pediatric									
Intravascular (Cerdiac)									
Trans-esoph, (Cardiac)	T								
intro-cerdac	1					1			
Peripheral vessel									
Urology (including prostate)	N	N	N		N	N	N	N	

N = new indication; P = proviously cleared by FDA: E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Pet 21 CFR 801.109)

ALPINION MEDICAL SYSTEMS Co., Ltd.

E-3

Division Signiforn
Division of Hadiotogical Devices
Office of In Vitro Diagnosus Device Evaluation and Salony

No. 288 1814

^{*} Combined: B/Color Coppler, B/PWD, B/Color Coppler(PWD; **Other: 3D, 4D

E-CUBE 15 with L3-12H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	8	H	PWD	CWD	Color Doppler	Power Doppler	Tissue Hermonic Imaging	Combined* (Specify)	Other** (Specify)	
Ophthalmic		П		$\overline{}$						
Felal										
Abdominal										
Intra-operative (Specify)	П									
Intra-operative (Neuro)	П									
Laparoscopic										
Pediatric				<u> </u>						
Small Organ (breast, testes, thyroid)	P	Р	P		Р	P		P		
Neonatal Cephalic	1									
Adult Cephalic		Т								
Trans-rectal	1									
Trans-veginal	1-									
Trans-webral	1									
Trans-eacph. (non-Card.)	1									
Musculo-skelelal (Conventional)	P	ρ	P		P	P		P		
Musculo-skeletal (Superficial)	P	P	P		P	Р		P		
intravascular	1									
Cardiac Adult	1	Т								
Cardiac Pediatric										
Intravascular (Cardiac)										
Trans-esoph. (Cardiac)	T	Π								
Intra-cardisc	1	1			T					
Peripheral vessel	F	P	P		P	P		P		
Urology (including prostate)	+									

N = new ladication; P = praviously cleared by FDA; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)	
(Division Sign-Off) Davisum or Rediciolytical Devices Office of in Visro Diagnostic Device Evaluation and Selection	E-4

^{*} Combined: B/Calor Doppler, B/PWD, B/Calor Doppler/PWD; **Oliver: 3D, 4D

E-CUBE 15 with SP1-5X Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	В	M	PWD	CWD	Golor Doppier	Power Doppler	Tissue Harmonic Imaging	Combined ⁴ (Specify)	Other** (Specify	
Ophthalmic ·	+-		 	t						
Felal									_	
Abdominal	N	N	N		N	N	N	N		
Intra-operative (Spectry)						_	<u> </u>			
Intra-operative (Neuro)										
Laparoscopic										
Pediatric	\top	\vdash								
Small Organ	\top					_				
(breast, tostes, thyroid)										
Neonstal Cephalic	\top									
Adult Caphalic	1									
Trans-rectal	\top						_			
Trans-vaginal	1-						-			
Trans-wethrai	1									
Trans-esoph. (non-Cart.)	\top									
Musculo-skeletal	\top	П								
(Conventional)										
Musculo-skeletal										
(Superficial)										
Intravascular										
Cardiac Adult	N ·	N	N	N	N	N	N	N	•	
Cardisc Pedistric			-							
Intravasoular (Cordiac)	1									
Trans-esoph. (Cardiac)										
Intra-cardiac										
Paripharal vessel	\Box		<u> </u>							
Urelogy (Including prostale)	\vdash	-		$\overline{}$					•	

N = new indication; P = previously cleared by FDA: E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

E-5

ALBINION MEDICAL SYSTEMS Co., Ltd.

(Ultrision Sign-Off)

Division of Ractioogical Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

^{*}Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWO; **Qther, 3D, 4D

E-CUBE 15 with L8-17X Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	8	M	PWD	CWD	Color Doppler	Power Dappier	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify	
Ophthalmic	1					 				
Felai	T									
Abdominal		\vdash								
Intra-operative (Specify)		_								
Intra-operative (Neuro)		\vdash								
Laparoscopic										
Pediatric	1									
Small Organ (breast, testes, thyrold)	N	N	N		N	N	-	N		
Neonatal Caphalic	1.									
Adult Cephalic	1									
Trans-rectal										
Trans-vaginal								-		
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skeletal (Conventional)	N	N	N		N	N		N		
Musculo-skeletal (Superficial)	N	N	N		N	N		N		
Intravascular										
Cardiac Adult										
Cardiac Pediatric										
intravascular (Cardiac)										
Trans-esoph, (Cardisc)	П									
Intra-cardiac										
Peripheral vessel	N	N	N		N	N		N		
Urology (including prostate)	\Box									

N = new indication; P = previously cleared by FDA; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OiVD)

Prescription User (Per 21 CFR 801.109)

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E-6

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with SC1-4H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify		
Ophlhalmic	T										
Fetal	N	N	N		N	N	N	N			
Abdominal	N	N	N		N	N	N	N			
Intra-operative (Specify)		Г									
Intra-operative (Neuro)						•					
Laparoscopic		Г					Î				
Pediatric	1										
Small Organ (breest, testes, thyroid)											
Neonatal Cephalic	T	\vdash			-						
Adult Cephatic	+										
Trans-rectal	\top	\vdash		_							
Trans-veginal	+	1									
Trans-urethral	1			_							
Trans-esoph. (non-Card.)	1			 							
Musculo-skeletal (Conventional)	T										
Musculo-skelelal (Superficial)											
Intravascular	\top				1						
Cardiac Adult	1					1					
Cardiac Pediatric	T								1		
Intravascular (Cardiac)											
Trans-esoph. (Cardiac)	1										
Intra-cardisc	1				T		1				
Peripheral vessel	\top					1					
Urology (including prostate)	N	N	N		N	N	N ,	N			

N = new indication; P = previously cleared by FDA; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.108)

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with E3-10H Transducer

intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mede of Operation										
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tisauo Harmonic Imaging	Combined*	(Specify)		
Ophthalmic											
Fetal											
Abdominal				<u>L</u>					ļ		
Intra-operative (Specify)	Г			,							
Intra-operative (Neuro)											
Laparosocpic									 		
Pediatric	Ĭ						<u> </u>		ļ		
Smail Organ (breast, testes, thyroid)											
Neonatal Cephalic				1							
Adult Cephalic	\top					Ι					
Trans-rectal	N	N	N		N	N	N	N			
Trans-veginal	N	N	N		N	N	N	N			
Trans-urethral		Γ.		\		┸			ļ		
Trans-esoph, (non-Card.)	Т					1			ļ		
Musculo-skelelal (Canventional)											
Musculo-skeletal (Superficial)											
intravescular								<u> </u>			
Cardiac Adult								<u> </u>	 		
Cerdiac Pediatric									1		
Intravescular (Cardiac)							-	-			
Trans-esoph. (Cardiac)								-			
Intra-cerdiac							-		+		
Peripheral vessel	T										
Urology (including prostate)							·				

N = new Indication; P = previously cleared by FDA; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

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Prescription User (Per 21 CFR 801.109)

ALPINION MEDICAL SYSTEMS Co., Ltd.

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Office ut in Vitro Diagnostic Device Evaluation and Bately

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/FWD; **Other: 3D, 4D